

1092058

OCT - 2 2009

510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

SonoSite, Inc.
21919 30th Drive SE
Bothell, WA 98021-3904

Corresponding Official:

Daina L. Graham
Vice President, Regulatory Affairs and Quality Assurance

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(425) 951-1275

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(425) 951-1201

Date prepared:

June 19, 2009

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite NanoMaxx™ Series Ultrasound System (*subject to change*)

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Medical image communications device	892.2020	LMD

3) Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that the System described in this Submission is substantially equivalent to a combination of the SonoSite Maxx Series Ultrasound System (K071134 and K082098), and the Philips Medical Systems (formerly Advanced Technology Laboratories) HDI® 5000 Ultrasound System (K034003 and K011224).

4) Device Description:

The SonoSite NanoMaxx Series Ultrasound System is a full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time

ultrasound data in 2D, Doppler, Color Power Doppler or in a combination of these modes. The hand-carried system weighs less than 6 pounds and has a touch screen interface with minimal controls to facilitate disinfection and cleaning.

The System provides measurement capabilities for anatomical structures and fetal biometry that provide information used for clinical diagnostic purposes. The system also includes the ability to measure the intima-media thickness (IMT) of the carotid artery using digital ultrasound images, which is used in conjunction with traditional risk assessment models to assess individual cardiovascular disease risk.

The system includes security support to facilitate HIPAA compliance.

The system includes a variety of accessories including a stand, dock featuring a video in/out port, a printer port, printer, VESA mounting arm and needle guide kits. The system includes two USB host supports for peripherals such as input devices and storage devices. Input devices include wired and wireless devices such as keyboard, and mouse. Storage devices include devices such as memory sticks, hard drives, and CDs. The system also features SiteLink™ allowing an additional method for the export of patient data.

The System/Transducer is capable of exceeding a TI or an MI of 1.0 in certain operating modes or mode combinations. The System monitor displays the current output level in terms of the bioeffects indices ("Mechanical Index [MI]" and "Thermal Index [TI]") in accordance with the AIUM/NEMA Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

Frequency Range:	1.0 – 13.0 MHz	
Transducer Types:	Linear array Curved array	Phased array

The SonoSite Maxx Series Ultrasound System is designed to comply with the following standards.

FDA Consensus Standards

Reference No.	Title
AAMI/ANSI/ISO 10993-1	ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing
AAMI/ANSI/ISO 10993-12	ISO 10993-12:2007, Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials
AAMI/ANSI/ISO 10993-10	ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
AAMI/ANSI/ISO 10993-11	ISO 10993-11:2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.
IEC 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988
IEC 60601-2-37	Medical Electrical Equipment -- Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (2001)

NEMA UD 2-2004	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
NEMA UD 3-2004	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine

Miscellaneous Standards

Reference No.	Title
ISO 9001:2008	Quality management systems – Requirements International Organization for Standardization (2008)
Title 21 CFR Part 820	Quality System Regulation – Medical Devices: Current Good Manufacturing Practice (CGMP); Final Rule
EN ISO 13485:2003	Medical devices – Quality management systems – Requirements for regulatory purposes (2003)
EN ISO 14971:2000	Medical devices – Application of risk management to medical devices (2000) (ISO 14971:2000)
RTCA D160E	Radio Technical Commission for Aeronautics: Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy

5) **Intended Use:**

The intended uses of the SonoSite NanoMaxx Series Ultrasound System as defined by FDA guidance documents, are:

Peripheral vessel
Fetal - OB/GYN
Abdominal
Musculo-skel. (Conventional)
Musculo-skel. (Superficial)
Cardiac
Pediatric
Small Organ (breast, thyroid, testicles, prostate)

Typical examinations performed using the SonoSite NanoMaxx Series Ultrasound System are:

Abdominal Imaging Applications

This system transmits ultrasound energy into the abdomen of patients using 2D, color Doppler (Color), color power Doppler (CPD) to obtain ultrasound images. The liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally.

Cardiac Imaging Applications

This system transmits ultrasound energy into the thorax of patients using 2D, to obtain ultrasound images. The heart, cardiac valves, great vessels, surrounding anatomical structures, overall cardiac performance, and heart size can be assessed for the presence or absence of pathology.

Gynecology and Infertility Imaging Applications

This system transmits ultrasound energy in the pelvis and lower abdomen using 2D, color Doppler, and color power Doppler (CPD) to obtain ultrasound images. The uterus, ovaries, adnexa, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally.

Interventional Imaging Applications

You can use the system for ultrasound guidance in drainage procedures, vascular line placement, peripheral nerve blocks, spinal nerve blocks and taps, amniocentesis and other obstetrical procedures, and provide assistance during abdominal, breast, and neurological surgery.

Obstetrical Imaging Applications

This system transmits ultrasound energy into the pelvis of pregnant women using 2D, color Doppler and color power Doppler (CPD) to obtain ultrasound images. The fetal anatomy, viability, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally. CPD imaging is intended for high-risk pregnant women. High-risk pregnancy indications include, but are not limited to, multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

Pediatric and Neonatal Imaging Applications

This system transmits ultrasound energy into the pediatric patients using 2D, color Doppler and color power Doppler (CPD) to obtain ultrasound images. The pediatric abdominal, pelvic, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Superficial Imaging Applications

This system transmits ultrasound energy into various parts of the body using 2D, color Doppler and color power Doppler (CPD) to obtain ultrasound images. The breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, and surrounding anatomical structures can be assessed for the presence or absence of pathology. This system can be used to provide ultrasound guidance drainage procedures, vascular line placement, peripheral nerve blocks, and spinal nerve blocks and taps.

Vascular Imaging Applications

This system transmits ultrasound energy into the various parts of the body using 2D, color Doppler and color power Doppler (CPD) to obtain ultrasound images. The carotid arteries, deep veins, and arteries in the arms and legs, superficial veins in the arms and legs, great vessels in the abdomen, and various small vessels feeding organs can be assessed for the presence or absence of pathology.

6) Technological Characteristics:

This device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D mages. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, velocity color) are the same as a combination of the predicate devices identified in item 3. Transducer patient contact materials are biocompatible.

This device conforms to the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (AIUM/NEMA UD 3-2004) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

I_{SPTA} (d)	720 mW/cm ²	Maximum
Tis/TIb/TIc	0.0 – 4.0	Range
Mechanical Index (MI)	1.9	Maximum
I_{SPPA} (d)	0 - 700 W/cm ²	Range

The limits are the same as predicate Track 3 devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Sonosite, Incorporated
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

OCT - 2 2009

Re: K092058

Trade/Device Name: SonoSite NanoMaxx™ Series Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasound pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 7, 2009
Received: July 8, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Elastography for SSA-790A Aplio XG v4.0R001 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C11n/8-5
C60n/5-2
L25n/13-6

L38n/10-5
P21n/5-1 Phased Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

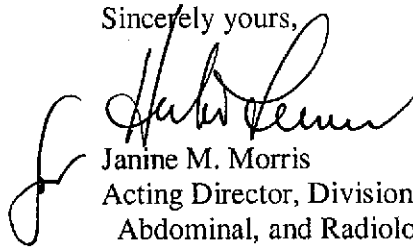
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

If you have any questions regarding the content of this letter, please contact Mr. Paul Hardy at (301) 796-6542.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over a large, stylized capital letter "J" that serves as a decorative initial.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): ~~TBD~~ K092058

Device Name: NanoMaxx: SonoSite NanoMaxx™ Series Ultrasound System

Indications for Use:

The SonoSite NanoMaxx Series Ultrasound System is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal; Pediatric; Small Organ (breast, thyroid, testicles, prostate); Peripheral Vessel; Intra-operative (abdominal organs, vascular); Musculoskeletal Conventional & Superficial, Cardiac Adult and Pediatric.

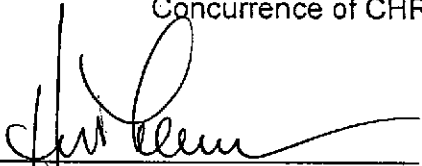
Prescription Use: X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CHRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K092058

Table 1.3-1 Diagnostic Ultrasound Indications for Use Form – SonoSite NanoMaxx™ Series Ultrasound System

System:		SonoSite NanoMaxx™ Series Ultrasound System							
Transducer:		N/A							
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows							
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N				N	B+CD, B+CPD	Note 1	
	Abdominal	N				N	B+CD, B+CPD	Note 1	
	Intra-operative (Abdominal Organs, Vascular)	N				N	B+CD, B+CPD	Note 1	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N				N	B+CD, B+CPD	Note 1	
	Small Organ (Breast, Thyroid, Testicles, Prostate)	N				N	B+CD, B+CPD	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N				N	B+CD, B+CPD	Note 1	
	Musculo-skeletal (Superficial)	N				N	B+CD, B+CPD	Note 1	
	Intravascular								
	Other (Specify)								
Cardiac	Cardiac Adult	N				N	B+CD, B+CPD	Note 1	
	Cardiac Pediatric	N				N	B+CD, B+CPD	Note 1	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel	N				N	B+CD, B+CPD	Note 1	
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, Tissue Harmonic Imaging, SonoHD, SonoMB Compound Imaging, Tissue Doppler Imaging. Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Includes imaging of spinal cord to provide guidance for central nerve block procedures.

Prescription Use (Per 21 CFR 801.109)

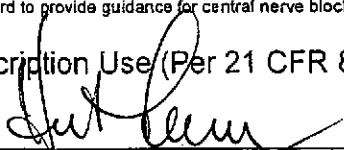

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 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K092058

Table 1.3-2 Diagnostic Ultrasound Indications for Use Form - C11n/8-5 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System							
Transducer:		C11n/8-5 8.0-5.0 MHz Curved Array							
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows							
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N				N	B+CD, B+CPD	Note 1	
	Intra-operative (Abdominal Organs, Vascular)	N				N	B+CD, B+CPD	Note 1	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N				N	B+CD, B+CPD	Note 1	
	Small Organ (Breast, Thyroid, Testicles, Prostate)	N				N			
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel	N				N	B+CD, B+CPD	Note 1	
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, SonoHD Imaging, SonoMB Compound Imaging. Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures, and expanded intended use for imaging guidance for peripheral nerve block procedures.

Prescription Use (Per 21 CFR 801.109)

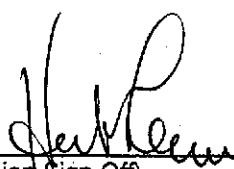

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 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K092058

Table 1.3-3 Diagnostic Ultrasound Indications for Use Form - C60n/5-2 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		C60n/5-2 5.0-2.0 MHz Curved Array						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows						
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N				N	B+CD, B+CPD	Note 1
	Abdominal	N				N	B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	N				N	B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N				N	B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	N				N	B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N				N	B+CD, B+CPD	Note 1
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, Tissue Harmonic Imaging, SonoHD Imaging, SonoMB Compound Imaging, Tissue Doppler Imaging. Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Includes imaging of spinal cord to provide guidance for central nerve block procedures.

Prescription Use (Per 21 CFR 801.109)

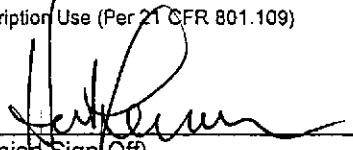

 (Division Sign Off)
 Division of Reproductive, Abdominal and
 Radiological Devices
 510(k) Number K092058

Table 1.3-4 Diagnostic Ultrasound Indications for Use Form – L25n/13-6 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System							
Transducer:		L25n/13-6 13.0-6.0 MHz Linear Array							
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows							
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N				N	B+CD, B+CPD	Note 1	
	Intra-operative (Abdominal Organs, Vascular)	N				N	B+CD, B+CPD	Note 1	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N				N	B+CD, B+CPD	Note 1	
	Small Organ (Breast, Thyroid, Testicles, Prostate)	N				N	B+CD, B+CPD	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N				N	B+CD, B+CPD	Note 1	
	Musculo-skeletal (Superficial)	N				N	B+CD, B+CPD	Note 1	
	Intravascular								
	Other (Specify)								
Cardiac	Cardiac Adult	N				N	B+CD, B+CPD	Note 1	
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel	N				N	B+CD, B+CPD	Note 1	
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, SonoHD Imaging, SonoMB Compound Imaging. Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and an expanded intended use for imaging guidance for peripheral nerve block procedures.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K092058

Table 1.3-5 Diagnostic Ultrasound Indications for Use Form - L38n/10-5 Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		L38n/10-5 10.05.0 MHz Linear Array Transducer						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows						
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N				N	B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	N				N	B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N				N	B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	N				N	B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	N				N	B+CD, B+CPD	Note 1
	Musculo-skeletal (Superficial)	N				N	B+CD, B+CPD	Note 1
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N				N	B+CD, B+CPD	Note
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N				N	B+CD, B+CPD	Note 1
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, SonoHD Imaging, SonoMB Compound Imaging. Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Includes imaging of spinal cord to provide guidance for central nerve block procedures.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K092058

Table 1.3-6 Diagnostic Ultrasound Indications for Use Form – P21n/5-1 Phased Array Transducer

System:		SonoSite NanoMaxx™ Series Ultrasound System						
Transducer:		P21n/5-1 5.0-1.0 MHz Phased Array Transducer						
Intended Use:		Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows						
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N				N	B+CD, B+CPD	Note 1
	Abdominal	N				N	B+CD, B+CPD	Note 1
	Intra-operative (Abdominal Organs, Vascular)	N				N	B+CD, B+CPD	Note 1
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N				N	B+CD, B+CPD	Note 1
	Small Organ (Breast, Thyroid, Testicles, Prostate)	N				N	B+CD, B+CPD	Note 1
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N				N	B+CD, B+CPD	Note 1
	Cardiac Pediatric	N				N	B+CD, B+CPD	Note 1
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel	N				N	B+CD, B+CPD	Note 1
Vessel	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, Tissue Harmonic Imaging, SonoHD Imaging, SonoMB Compound Imaging, Tissue Doppler, Color Doppler includes Color Velocity Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K092058